

Version 2.0



Abstract

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PI Title:

Project Title: OXYGEN SATURATION MONITORING IN NEONATES

Abstract: *DESCRIPTION (Adapted from the Investigator's Abstract): Maintaining adequate oxygenation for neonates who need ventilatory support is essential for optimal health outcomes in this vulnerable group. To avoid oxygen toxicity, neonates are aggressively weaned from the ventilator. Neonates on ventilators are more sensitive to stimuli and frequently develop desaturation episodes, apnea, and bradycardia. They are at greater risk of hypoxemia, in part because of their high fetal hemoglobin level. Accurate and continuous oxygen saturation (SO₂) status is crucial. The aims of this study are: 1. to examine the effects of using fiberoptic umbilical catheters to monitor arterial and venous SO₂ (SaO₂ and SvO₂) on ventilatory weaning and oxygenation complications including hyperoxemia and hypoxemia; 2. to validate bedside monitoring of SaO₂, SvO₂, and pulse oximetry (SpO₂) by examining: a.) the effect of fetal hemoglobin on the accuracy of SO₂ monitoring, using a gold standard co-oximeter, and b.) the association between SO₂ and oxygen tension values in neonates; 3. to examine the effects of ventilatory weaning on SO₂ readings and vagal tone as measured by ECG R-R intervals. Neonates who need an umbilical arterial catheter (UAC) and an umbilical venous catheter (UVC) will be randomly assigned to the fiberoptic group (n=120) or the control group (n=120) based on five prenatal and five birth characteristics using the minimization method. Ventilatory support and oxygenation complications will be followed. The fiberoptic group will be monitored on SaO₂ and SvO₂ through fiberoptic catheters, in addition to SpO₂. These measurements will be validated at 4-hour intervals against a co-oximeter, taking into account the effects of fetal hemoglobin on SO₂. A bedside computer will be used to continuously record SaO₂, SvO₂, SpO₂, and ECG R-R intervals. Using a computerized coding system, a data collector along with a video camera will continuously record*

bedside care events including each ventilatory weaning attempt. This study will determine whether SaO2 and SvO2 monitoring will improve the success of ventilatory weaning and reduce oxygenation complications. In addition, the study will examine oxygen utilization and hemodynamic function when neonates adapt to extrauterine life during ventilatory support.

Thesaurus Terms:

catheterization, diagnosis design /evaluation, newborn human (0-6 weeks), oximetry, oxygen tension, patient monitoring device, respirator clinical trial, fiber optics, hemoglobin F, hypoxia neonatorum, outcomes research, respiratory disorder diagnosis, respiratory gas analyzer, respiratory hypoxia clinical research, electrocardiography, human subject

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